ATTACHMENT 68

This document serves as a platform to respond to and discuss an FAQ document that has been issued by Intuitive Surgical® regarding the repair service of the EndoWrist™ instruments. We will address each point directly below but would like to provide a few overview points before we begin:

1 – The document was created for an international audience (I.e. outside of USA), presumably European. The FDA is never mentioned, only CE. The contact information is for a Switzerland based representative. It is unclear if any of the points made by Intuitive would be viable for the USA market, however we will address them.

2 – It appears that Intuitive believes (or may be trying to enroll their customer in the belief) that the repair process is limited to merely resetting the count and that no other effort is expended. These insinuations could not be further from the truth.

Each instrument receives several rounds of assessment and testing during the repair process. All of this is done in a clean, modern facility. The design and repair process is fully certified against all of the relevant ISO standards including 14971 (Risk Management), 13485 (manufacturing), 10993 (Bio Compatibility), 9001 (Quality Management) and more.

Lastly, beyond the intensive efforts spent to build a world class process a notified-body agency was brought in to audit the process to prove that all possible quality efforts are being followed.

The *italicized* text below is quoted directly from the Intuitive Surgical® document (FAQs for UNAUTHORIZED REPROGRAMMED INSTRUMENTS June15, 2017 1033322 Rev D).

The responses below will typically include 2 areas:

- Response (**R**): a direct response to the claims made in each section and
- Information Requests (**IQ**): a set of possible information requests for the hospital to consider making of Intuitive in order to provide clarity regarding Intuitive's statements.

FAQs for UNAUTHORIZED REPROGRAMMED INSTRUMENTS June15, 2017

Objective of this FAQ Document: Educate users of da Vinci® EndoWrist® instruments about risks associated with the use of unauthorized reprogrammed instruments and communicate where to direct further inquiries.

1.) What is an unauthorized reprogrammed instrument?

Intuitive Surgical has become aware of 3rd party companies acquiring and servicing da Vinci reusable instruments that are about to expire. The instruments are reprogramed with additional uses, beyond their original validated number of lives.

R1 - The instruments are not acquired (i.e. the hospital maintains ownership of the instruments at all times). This is a key component. Traceability and ownership are retained, and therefore, this service falls under the scope of a repair. The same scope includes any equipment currently being serviced for the hospital.

R2 - The repair processes have been formally certified per ISO standards and independent life testing of the instruments have been performed to confirm the claims of safe extended usability.

IQ1 - It may be useful to have Intuitive provide the regulatory documentation that states that the instruments have a validated set of lives.

2.) Does Intuitive Surgical support the unauthorized reprogramming of instruments?

No. To ensure the highest level of patient safety and product quality, Intuitive Surgical sells its products and services only directly to hospitals or through authorized Intuitive Surgical distributors. Due to safety concerns, Intuitive Surgical does not recommend the procurement of its products and services through unauthorized parties or channels.

R1 - The repair process is built from several ISO standard practices including a complete safety risk management file following the ISO 14971 standard for medical devices. As well as extensive safety testing and failure modes analysis. The results of all analysis and testing was that the serviced instruments do not present any elevated or unacceptable safety risk.

3.) What are the risks involved with use of unauthorized reprogrammed instruments?

Intuitive Surgical advocates "Patients First…Always".

In Robotically Assisted Surgery, the instruments under surgeon control have been carefully engineered to maintain a specific level of performance during every use. As such, all Intuitive Surgical EndoWrist® products are rigorously tested, reviewed and cleared by regulatory authorities to achieve a targeted level of safety, precision, and dexterity over the validated number of instrument lives. Beyond this validated useful life, the accumulated effects of normal wear and tear will impact the instrument's performance. This gradual degradation occurs both from use in surgery as well as repeated chemical and thermal exposure during the cleaning and sterilization cycles required between uses, which is why it is so important to adhere to the validated number of uses.

R1 - Regarding precision and dexterity - The precision and dexterity were validated in the surgical control system, not the instruments. The instruments are standard laparoscopic instruments adapted to be controlled by the host system instead of directly by the human hand.

R2 - Regarding instrument degradation - Most of the instruments are "validated" for 10 uses. This would seem to imply one of two things:

A) either they wear evenly and degrade at approximately the same rate; or
B) the 10 uses is based on the weakest link that degrades the fastest.

It would be a difficult argument to make that a pair of non-energized, soft tissue forceps degrades as fast as a RF energized scissor that cauterizes and cuts. This would then lend itself to the second case; that the 10 uses is based on the weakest link. Since the specific tool ends vary in form and function, this weak-link theory is a direct contradiction to their validated "specific level of performance" statement. If one tool end receives far less wear, then it would be able to sustain a longer life in the acceptable "specific level of performance". They could make the argument that there is a different component in the instrument that dictates the validated "safe" amount of lives. However, the instruments

are all made of identical components apart from the tool specific components at the distal tip. Therefore, if the specific tool does not set the pace, and the rest of the instruments are built identically, it would require a universal “safe” lifespan. We know that some instruments are available for 15 lives, 30 lives, and 100 closures. This, again, is conflicting to the “validated” life span of these instruments.

We believe that periodic service and continued use is the only way to achieve the appropriate usage/value from the instrument.

IQ1 - It may be useful to ask for clarification from Intuitive on the conflicting claims with regard to degradation and to provide documentation on “validated number of instrument lives”.

IQ2 - Recommend that Intuitive provide the documentation confirming the instruments were only cleared for the specific number of uses, as this is not how devices are typically cleared by regulatory authorities.

Examples of instrument degradation include but are not limited to:

Unintuitive motion (i.e. instruments do not track well with master manipulators; sudden undesired motions or stalls

R3 - Sudden undesired motions could only be a flaw in the control system. The entire surgical system was validated, tested, and cleared to be 100% under the control of the trained physician. The instruments are passive accessories that only perform the directed actions of the surgeon. An undesired movement would be a potential catastrophic risk. The opposite (stalls or lack of range of motion) could be a result of the instrument. However, this is a safe error state. This lack of motion would be predictable and observable by the physician and is, in no way, different from any manual laparoscopic instrument.

Insufficient grip force;

R4 - Grip force is controlled by the host system which relies only on the instruments cables being properly adjusted. This state is checked multiple times during the repair process and cables are tightened and aligned should they need it.

Dull or damaged scissor blades;

R5 - Damaged and dull scissor blades are an issue that affects all laparoscopic scissors, not just EndoWrists™. This issue has been being addressed in repairs for decades.

Broken/failed components; could result in fractured components

R6 - Fractures or breaks, when they have been observed (in a base of thousands of instrument lives) have consistently been traced to misuse or mishandling, sometimes during sterilization. These faults due to instrument damage also occur during the first 10 lives, as they are not a function of instrument uses but of the design itself. No data has indicated that this kind of damage is any more likely for a serviced instrument.

Any of these product performance issues could impact the surgeon during the procedure and result in safety risks to the patient.

Furthermore, unknown handling, non-validated reprocessing methods, and transit conditions for instruments by these unauthorized 3rd party companies have the potential to damage instruments.

R7 - Our service is not a reprocessing, it is a repair. The term "Reprocessing" is used ambiguously here. Third Party Reprocessors are required to receive a new regulatory clearance to reprocess and refurbish Single-Use devices. However, these are clearly not single-use devices. They are intended to be cleaned and sterilized (Reprocessed). The reprocessing instructions for the instruments remain identical.

R8 - Shipping issues are non-existent. The instruments are quite sturdy, and the hospital performs its own packing and is aware of the quality of the transit conditions. The instruments encounter no greater risk being sent for repair than they do when they are shipped to the hospital initially by Intuitive.

4.) What are the regulatory risks (CE Mark, etc.) involved with use of unauthorized reprogrammed instruments?

Regulatory clearances for all da Vinci Instruments specify the allowable number of uses for which the instrument has been validated. Use of the product beyond the validated number of uses would require a new validation and regulatory review and clearance. For details regarding the validation testing see question #3.

R1 - There is no evidence that the repairs we perform would require "a new validation and regulatory review" as the instructions for use and reprocessing instructions remain identical before and after the repair service.

IQ1 - It may be useful to request copies of these regulatory clearances that specify an allowable number of uses.

In addition, modification by an outside party can impact support, traceability and monitoring of the device by Intuitive Surgical. This can impact a customer being notified of a potential device recall or other updates to device labeling.

Intuitive Surgical's products CE Mark as well as other applicable regulatory requirements for da Vinci instruments only cover instruments that have been manufactured by the legal manufacturer for the validated number of uses. The regulatory clearance does not cover instruments reprogrammed to extend the number of uses.

R2 - The CE Mark information is irrelevant to the USA market.

R3 - Traceability of the instruments is always maintained. The hospital retains their own instruments. Any recalls or notices will not be impacted.

IQ2 - The hospital may want to ask Intuitive to provide regulatory documentation stating that only "instruments that have been manufactured by the legal manufacturer for the validated number of uses" are covered by the FDA.

5.) Will a hospital using unauthorized reprogrammed instruments receive quality notifications related to those products from Intuitive Surgical?

No. As a medical device company, Intuitive Surgical is responsible for tracking the distribution of its devices. This enables us to identify the location of all affected products in the event of a product issue or recall. Reprogrammed products are no longer traceable through our systems. Thus, customers could have product affected by a recall but would not receive a notification because the customer cannot be identified.

R1 - All instruments remain owned and controlled by the hospital, just like any other serviced device, and they will receive and respond to the notice.

R2 - Traceability is meticulously maintained by the ISO certified repair facility. Traceability is never lost. Model/serial numbers both printed on the case and programmed into the instrument are meticulously maintained along with the instrument. This is formally documented during the repair process using travelers and formal test logs.

R3 - NOTE: If this point was accurate then every serviced medical device of every kind would be "untraceable". Nothing about the traceability is affected in any way by the service.

6.) What internal hospital policies may be violated in acquiring/using unauthorized reprogrammed product?

Acquiring da Vinci surgical products or services through unauthorized channels may also violate the hospital's internal policies, including but not limited to using a medical device that does not have regulatory clearance. Contact the Risk Management department for your hospital's specific policy information and potential implications to patient consent for the use of an altered and/or non-CE Marked device on the patient.

R1 - A more useful and relevant action would be to consult the Hospital's policies for equipment servicing.

R2 - The device has a regulatory clearance for form, function, safety and efficacy, none of which are altered by the repair process.

- Using an instrument that has been repaired does not, and has never, affected its regulatory clearance, as long as its intended use has not been altered.
- EndoWrist™ intended use statement mentions nothing about number of lives. It is declared a reusable instrument.

7.) Does Intuitive Surgical warranty unauthorized reprogrammed instruments? And how does their use impact Intuitive's System Service obligation?

No. For the reasons stated above, the use of instruments or accessories purchased through unauthorized sources with the da Vinci Surgical System, or the servicing thereof by any unauthorized party, will void the warranty for the instrument, accessory, System, and/or associated services. Intuitive will no longer have an obligation to service the System and may thus discontinue servicing the System.

> **R1 -** Hospitals may wish to consult their legal resources regarding their ability to repair the instruments and devices that they own without potential for loss of service by the OEM. Voiding a system-level warranty is usually only applicable when an unauthorized accessory is used on the system. The repair process retains the original instrument and memory device, therefore it could never be considered an unauthorized accessory. The instrument repaired is, and will always be, the same instrument that was used on the system.
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> NOTE – this statement appears to imply that repairing ANY accessory would result in a voided warranty on the host system. An example of this would be; repairing cameras would void the warranty on the camera console. Hospitals commonly have these devices and many others serviced.

8.) What should you do if you discover the use of unauthorized reprogrammed, instrument at your hospital or if you have additional questions on this FAQ?

To ensure ongoing patient safety and product performance, the instrument(s) should be returned as per the standard RMA (Return Material Authorization) process. Intuitive Surgical will provide credit via a credit memo to the customer for the reprogrammed lives remaining on the unauthorized reprogrammed instrument.

> **R1 -** Hospitals may wish to compare the value of Intuitive's suggested actions opposed to the value of receiving significant savings and a secondary option should the OEM be unable to service the robotic system in the future.

FINAL COMMENTS

Regarding EndoWrist 510K

The description of the EndoWrists™, directly from their 510k states (emphasis ours):
“Device Description: The working ends and elements of the Intuitive Surgical™ Endoscopic Instruments and Accessories are essentially identical in size and shape to the predicate devices referenced **and represent standard embodiments of standard surgical tools** modified for use with the Intuitive Surgical™ Endoscopic Instrument Control System.”

NOTE - Predicate device is a 1970’s laparoscopic instrument

This statement would appear to be in direct opposition to the claims made throughout this document. Standard surgical tools have no defined lives or performance standards that cannot be directly observed and judged by the trained physician

Regarding Component Degradation

As component degradation was brought up multiple times we would like to address the specific components of the tools for those of you for whom this information would be useful:

- Housing:
  - Polysulfone compound
    - Known for toughness and stability at high temps
- Shaft:
  - Multi-layer fiber glass reinforced composite with “E” glass
    - one of the most widely used fiberglass composites
    - Known for its heat resistance and electrical insulating properties
- Tool End:
  - 17-4 stainless
    - Used in graspers for its high level of hardness & corrosion resistance
  - 420 chromium stainless
    - Used in scissors for its even harder steel to aid in retaining sharp edges
- Plastics:
  - Polyetherimide (e.g. Ultem)
    - Known for high strength, temperature resistance, and dielectric strength
- Manipulation Cables:
  - Tungsten ‘rope’ made of flexible, but very high strength, fibers
    - This design and material resists stretching, which prevents the tool-end from “loosening”